7.1 Site Monitoring Visits

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1. Purpose

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of its performance or compliance to the scientific and ethical standards specified in the approved protocol.

2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the IRB approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

3. Responsibility

It is the responsibility of the IRB to perform or designate some qualified agents to perform on its behalf on-site inspection of the research projects it has approved.

The IRB members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

4. Flow chart

No.	Activity	Responsibility
1	Selection of study sites ↓	IRB members and Chairperson
2	Procedures before the visit ↓	IRB members and/or representative
3	Procedures during the visit ↓	IRB members and/or representative
4	Procedures after the visit ↓	IRB members and/or representative
5	Present the findings to the Full Board	IRB members and/or representative

5. Detailed instructions

5.1. Selection of study sites

- Review periodically the database files of the submitted/approved study protocols.
- Select study sites needed to be monitored based on the following criteria:
  - New study sites

- Reports of remarkable serious adverse events
- Number of studies carried out at the study sites.
- Frequency of protocol submission for IRB review
- Non-compliance or suspicious conduct
- Frequently fail to submit final reports

5.2. Before the visit

The IRB representatives will:

- Contact the site to notify them that they will be visiting them. At that time, the investigator/monitor and the site will coordinate a time for the site evaluation visit,
- Make the appropriate travel arrangements,
- Review the IRB files for the study and site,
- Make appropriate notes, and/or
- Copy some parts of the files for comparison with the site files.

5.3. During the visit

- Get a checklist (EPHI-IRB AF 01-021/02.0)
- The IRB representatives will
  - Review the informed consent document to make sure that the site is using the most recent version,
  - Review randomly the subject files to ensure that subjects are signing the correct informed consent,
  - Observe the informed consent process, if possible,
  - Observe laboratory and other facilities necessary for the study at the site,
  - Review the IRB files for the study to ensure that documentation is filed appropriately,
  - Collect views of the study participants,
  - Debrief the visit report/comments, and
  - Get immediate feedback.

5.4. After the visit

The IRB representative will:

- Write a report/comment (use the form EPHI-IRB AF 01-021/02.0) within 2 weeks describing the findings during the audit,
- Forward a copy of the site visit report to the ‘site monitoring’ file for Full Board review,
- Send a copy of the report to the site for their files, and
- Place the report in the correct site files.

5.5. Present the inspection results to the Full Board

- Consult with the IRB secretariat,
- Schedule the presentation in the meeting agenda, and
- Present the results of on-site inspections to the Full Board.

5.6. Type of decision

☐ No further action

☐ Request Information

☐ Recommend further action

6. Glossary

IRB representatives	Many IRB rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of SERO to perform the tasks on their behalf and later report their findings to IRB.
Monitoring visit	An action that IRB or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

7. References

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.

8. Annex

Annex 1: Checklist of a Monitoring Visit
(EPHI-IRB F 01-021/02.0)

Protocol No.: EPHI-IRB-☐☐☐-☐☐☐☐	Date of the Visit:
Study Title:	
Principal Investigators:	Phone:
Institute:	Address:
Sponsor:	Address:
Total number of expected subjects:	Total subjects enrolled:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Are Informed Consents recent? ☐ Yes ☐ No	Comment:
Any adverse events found? ☐ Yes ☐ No	Comment:
Any protocol non-compliance /violation? ☐ Yes ☐ No	Comment:
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:
Duration of visit: ……. hours	Starting from: Finish:
Decision ☐ No further action required ☐ Request information ☐ Recommend further action	Comment:

Name of surveyors (IRB member/ representatives and companion) and signature	1. Name: ……. Signature …….. Date: ……. 2. Name ……. Signature ……. Date: …….
Completed by: Name: ……. Signature: ……	Date: ……